Deliberative Process / Ex. 5

From: Cote, Ila

Sent: Tuesday, March 01, 2016 7:49 PM **To:** Johnson, Ann@epa.gov>

Cc: Flowers, Lynn <Flowers.Lynn@epa.gov>; Fegley, Robert <Fegley.Robert@epa.gov>;

Johnson, Amaris < Johnson. Amaris@epa.gov >; Thomas, David

<Thomas.David@epa.gov>; Mushkolaj, Iliriana <Mushkolaj.Iliriana@epa.gov>; Miles-

McLean, Stuart < Miles-Mclean. Stuart@epa.gov>; Miller, Gregory

< Miller. Gregory@epa.gov>; Foster, Stiven < Foster. Stiven@epa.gov>; Ramasamy,

Santhini < Ramasamy. Santhini@epa.gov >

Subject: Re: Interagency review: Arsenic in Rice - responses/revisions (HHS/FDA)

Deliberative Process / Ex. 5

Personal Phone / Ex. 6

On Mar 1, 2016, at 3:39 PM, Johnson, Ann < Johnson. Ann@epa.gov> wrote:

See below. Looks like we are not being included in a call with USDA.

ORD - Can you provide a contact?

From: InteragencyReviews

Sent: Tuesday, March 01, 2016 5:20 PM **To:** Johnson, Ann@epa.gov>

Cc: InteragencyReviews < InteragencyReviews@epa.gov>

Subject: FW: Interagency review: Arsenic in Rice - responses/revisions

(HHS/FDA)

Hi Ann,

Here's the response from OMB -- share as you see fit with your reviewer community.

Please send along contact info for an EPA senior policy official and tell me if you have concerns with the characterization of EPA's position.

Thanks,

--Stuart

Stuart Miles-McLean | Office of Regulatory Policy & Management | Office of Policy | Office of the Administrator

202.564.6581 | 3512J WJC North | Mail Code 1803 | 1200 Pennsylvania Avenue NW | Washington, DC 20460

From: Wise, Julie [mailto: Ex. 6

Sent: Tuesday, March 01, 2016 4:32 PM

To: InteragencyReviews < InteragencyReviews@epa.gov>
Cc: Corrales, Mark < Corrales.Mark@epa.gov>; Balserak, Paul
<Balserak.Paul@epa.gov>; Owens, Nicole < Owens.Nicole@epa.gov>

Subject: RE: Interagency review: Arsenic in Rice - responses/revisions

(HHS/FDA)

Thanks, Stuart.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Thanks.

Julie A. Wise Office of Information and Regulatory Affairs Executive Office of the President

Phone: (202) 395-7151

From: InteragencyReviews

[mailto:InteragencyReviews@epa.gov]
Sent: Tuesday, March 01, 2016 3:37 PM

To: Wise, Julie **Ex. 6**

Cc: Corrales, Mark < Corrales. Mark@epa.gov>; Balserak, Paul

<Balserak.Paul@epa.gov>; Owens, Nicole

<<u>Owens.Nicole@epa.gov</u>>; InteragencyReviews

<InteragencyReviews@epa.gov>

Subject: RE: Interagency review: Arsenic in Rice -

responses/revisions (HHS/FDA)

Good afternoon Julie,

EPA staff who participated in the interagency meeting yesterday asked me to follow-up with you, because they were left with the impression that there may be opportunities for additional interagency interactions regarding some of the issues, documents, and data discussed.

The Agency wants to be clear that these matters are of interest to EPA and we want to ensure that we receive notice of, and be included in, any further interagency discussions, including discussion beyond the staff level. Please let us know if you need a senior management contact.

Thank you, --Stuart

Stuart Miles-McLean | Office of Regulatory Policy & Management | Office of Policy | Office of the Administrator
202.564.6581 | 3512J WJC North | Mail Code 1803 | 1200 Pennsylvania
Avenue NW | Washington, DC 20460

From: Wise, Julie [mailto] Ex. 6

Sent: Monday, February 29, 2016 3:17 PM

To: InteragencyReviews < subject: RE: EPA Agenda Items -- RE: Interagency review:

Arsenic in Rice - responses/revisions (HHS/FDA)

Thanks - I'll share this with FDA.

Julie A. Wise Office of Information and Regulatory Affairs Executive Office of the President

Phone: (202) 395-7151

From: InteragencyReviews

[mailto:InteragencyReviews@epa.gov]

Sent: Monday, February 29, 2016 3:16 PM

To: Wise, Julie Ex. 6

Cc: WCTS - OBPA USDA Reg < <u>usdareg@obpa.usda.gov</u>>; Poe, Michael - OBPA (<u>Michael.Poe@obpa.usda.gov</u>)

<Michael.Poe@obpa.usda.gov>; Rayford, Linwood L.

<<u>Linwood.Rayford@sba.gov</u>>; Balserak, Paul

<Balserak.Paul@epa.gov>;

robert.hinchman@usdoj.gov; Smith, Mark - OBPA

(Mark.Smith@obpa.usda.gov)

<Mark.Smith@obpa.usda.gov>;

kevin.bromberg@sba.gov; Corrales, Mark

<Corrales.Mark@epa.gov>; Owens, Nicole

<Owens.Nicole@epa.gov>; InteragencyReviews

<InteragencyReviews@epa.gov>

Subject: EPA Agenda Items -- RE: Interagency review: Arsenic in Rice - responses/revisions (HHS/FDA)

Julie,

EPA has two agenda items for the meeting this afternoon:

- <!--[if !supportLists]--><!--[endif]-->Estimating risk for individuals with greater than average rice consumption and EO 12898
- <!--[if !supportLists]--><!--[endif]-->FDA next steps and timing

--Stuart

Stuart Miles-McLean | Office of Regulatory Policy & Management |
Office of Policy | Office of the Administrator
202.564.6581 | 3512J WJC North | Mail Code 1803 | 1200
Pennsylvania Avenue NW | Washington, DC 20460

From: InteragencyReviews

Sent: Monday, February 29, 2016 11:08 AM

To: Wise, Julie

Ex. 6

Cc: WCTS - OBPA USDA Reg <usdareg@obpa.usda.gov>; Poe, Michael - OBPA (Michael.Poe@obpa.usda.gov) <Michael.Poe@obpa.usda.gov>; Rayford, Linwood L.

<Linwood.Rayford@sba.gov>; Balserak, Paul

<Balserak.Paul@epa.gov>;

robert.hinchman@usdoj.gov; Smith, Mark - OBPA

(Mark.Smith@obpa.usda.gov) <Mark.Smith@obpa.usda.gov>;

kevin.bromberg@sba.gov; InteragencyReviews

<InteragencyReviews@epa.gov>; Corrales, Mark

<Corrales.Mark@epa.gov>; Owens, Nicole

<Owens.Nicole@epa.gov>

Subject: RE: Interagency review: Arsenic in Rice - responses/revisions (HHS/FDA)

Good morning Julie,

The proposed 3:30 to 5:00 time will work for EPA and we expect to have several people on the call this afternoon.

If our subject matter experts are able to pull something together on such short notice, we will try to send along some issues for discussion before the meeting.

--Stuart

Stuart Miles-McLean | Office of Regulatory Policy & Management | Office of Policy | Office of the Administrator 202.564.6581 | 3512J WJC North | Mail Code 1803 | 1200 Pennsylvania Avenue NW | Washington, DC 20460

From: Wise, Julie [mailto] Ex. 6

Sent: Monday, February 29, 2016 10:08 AM

To: Smith, Mark - OBPA (Mark.Smith@obpa.usda.gov)

<Mark.Smith@obpa.usda.gov>;

kevin.bromberg@sba.gov; InteragencyReviews

<InteragencyReviews@epa.gov>

Cc: Owens, Nicole < Owens. Nicole@epa.gov>; WCTS -

OBPA USDA Reg <usdareg@obpa.usda.gov>; Poe,

Michael - OBPA (Michael.Poe@obpa.usda.gov)

<Michael.Poe@obpa.usda.gov>; Rayford, Linwood L.

<Linwood.Rayford@sba.gov>; Balserak, Paul

<Balserak.Paul@epa.gov>; robert.hinchman@usdoj.gov

Subject: RE: Interagency review: Arsenic in Rice - responses/revisions (HHS/FDA)

All,

Just checking again for availability this afternoon between 3:30-5pm for a call with FDA (I'm guessing that we should plan on an hour). This block of time works for EOP and SBA, but I haven't heard back from USDA or EPA.

If today doesn't work, FDA has indicated that 2pm on Wednesday is an option.

Thanks.

Julie A. Wise Office of Information and Regulatory Affairs Executive Office of the President

Phone: (202) 395-7151

From: Wise, Julie

Sent: Friday, February 26, 2016 4:43 PM

To: Smith, Mark - OBPA

(Mark.Smith@obpa.usda.gov)

<<u>Mark.Smith@obpa.usda.gov</u>>; Bromberg,

Kevin L. (kevin.bromberg@sba.gov)

<kevin.bromberg@sba.gov>; EPA

(InteragencyReviews@epa.gov)

<InteragencyReviews@epa.gov>

Cc: 'Owens, Nicole' < Owens. Nicole@epa.gov>;

'WCTS - OBPA USDA Reg'

<usdareg@obpa.usda.gov>; Poe, Michael -

OBPA (Michael.Poe@obpa.usda.gov)

<<u>Michael.Poe@obpa.usda.gov</u>>; 'Rayford,

Linwood L.' <Linwood.Rayford@sba.gov>;

'rees.sarah@epa.gov' <rees.sarah@epa.gov>;

Balserak, Paul (Balserak, Paul@epa.gov)

<Balserak.Paul@epa.gov>; Hinchman, Robert

(SMO) (Robert.Hinchman@usdoj.gov)

<Robert.Hinchman@usdoj.gov>

Subject: RE: Interagency review: Arsenic in Rice

responses/revisions (HHS/FDA)

All,

In the interest of time, we are working with FDA to set up a call on Monday afternoon to discuss the latest passback (sorry for the short notice).

If you are interested in participating, please let me know your availability for a 1 hour call between 3-5pm this Monday (2/29). If there are particular issues that you would like to

discuss on the call, please let me know so that FDA can have the right experts on the line.

Thanks,

Julie A. Wise Office of Information and Regulatory Affairs Executive Office of the President

Phone: (202) 395-7151

From: Wise, Julie

Sent: Monday, February 22, 2016 5:28

PM

To: Smith, Mark - OBPA

(Mark.Smith@obpa.usda.gov)

<Mark.Smith@obpa.usda.gov>;

Bromberg, Kevin L.

(kevin.bromberg@sba.gov)

<<u>kevin.bromberg@sba.gov</u>>; EPA

(InteragencyReviews@epa.gov)

<InteragencyReviews@epa.gov>

Cc: 'Owens, Nicole'

<Owens.Nicole@epa.gov>; 'WCTS -

OBPA USDA Reg'

<usdareg@obpa.usda.gov>; Poe,

Michael - OBPA

(Michael.Poe@obpa.usda.gov)

<Michael.Poe@obpa.usda.gov>;

'Rayford, Linwood L.'

<Linwood.Rayford@sba.gov>;

'rees.sarah@epa.gov'

<rees.sarah@epa.gov>; Balserak, Paul

(Balserak.Paul@epa.gov)

<<u>Balserak.Paul@epa.gov</u>>; Hinchman,

Robert (SMO)

(Robert.Hinchman@usdoj.gov)

<Robert.Hinchman@usdoj.gov>

Subject: RE: Interagency review: Arsenic in Rice - responses/revisions (HHS/FDA)

All,

Following up on the email I sent last Friday, attached are <u>clean</u> versions of:

- 1. <!--[if !supportLists]--><!--[endif]-->Risk assessment,
- <!--[if !supportLists]--><!-[endif]-->Cereal guidance, and

3. <!--[if !supportLists]--><!--[endif]-->Supporting document for the guidance.

Please put comments and suggested edits in these clean versions so that changes can be easily identified.

Thanks.

Julie A. Wise Office of Information and Regulatory **Affairs** Executive Office of the President

Phone: (202) 395-7151

From: Wise, Julie

Sent: Friday, February 19, 2016 4:31 PM

To: Smith, Mark - OBPA (Mark.Smith@obpa.usda.gov) <Mark.Smith@obpa.usda.gov>;

Bromberg, Kevin L.

(kevin.bromberg@sba.gov)

<kevin.bromberg@sba.gov>; EPA (InteragencyReviews@epa.gov)

<InteragencyReviews@epa.gov>

Cc: Owens, Nicole

<Owens.Nicole@epa.gov>; WCTS -

OBPA USDA Reg

<usdareg@obpa.usda.gov>; Poe,

Michael - OBPA

(Michael.Poe@obpa.usda.gov)

<Michael.Poe@obpa.usda.gov>;

'Rayford, Linwood L.'

<Linwood.Rayford@sba.gov>;

'rees.sarah@epa.gov'

<rees.sarah@epa.gov>; Balserak, Paul

(Balserak.Paul@epa.gov)

<Balserak.Paul@epa.gov>; Hinchman,

Robert (SMO)

(Robert.Hinchman@usdoj.gov)

<Robert.Hinchman@usdoj.gov>

Subject: Interagency review: Arsenic in Rice - responses/revisions (HHS/FDA)

Good afternoon,

Attached are responses/revisions from HHS/FDA on the Arsenic documents.

Please provide any remaining comments or suggested edits by COB Monday (3/7). It has been about 2 months since we have reviewed the documents, so please let me know if a call with FDA would be helpful. Likewise, if it would be helpful to have an interagency call (without FDA) to discuss our collective comments, let me know and we can set something up for late next week.

Note: FDA continues to remind me that the risk assessment and underlying data have been the subject of a FOIA request and they are anxious about timing.

Attached:

- 1. <!--[if !supportLists]--><!--[endif]-->Response memo
- <!--[if !supportLists]--><!-[endif]-->Revised arsenic in rice
 RA
- 3. <!--[if !supportLists]--><!--[endif]-->Revised arsenic in rice guidance
- 4. <!--[if !supportLists]--><!--[endif]-->Revised supporting document for guidance
- <!--[if !supportLists]--><!--[endif]-->Response to peer review comments

Enjoy the weekend,

Julie A. Wise
Office of Information and Regulatory
Affairs
Executive Office of the President

Phone: (202) 395-7151

From: Flowers, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1A4411C874D041B9A8BADFC32B91BD70-FLOWERS, LYNN]

Sent: 8/26/2016 7:49:49 PM

To: Crofton, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a23824ad1d466c92e9a86b0485a93e-Crofton, Kevin]; Bahadori, Tina

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Cowden, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=4cccc2629cb043e0901c6b5f61344e9c-Cowden, John]; Vandenberg, John

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=dcae2b98a04540fb8d099f9d4dead690-Vandenberg, John]; Ross, Mary

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=98359cd1f66f46ec91d327e99a3c6909-Ross, Mary]; Bussard, David

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=cf26b876393e44f38bdd06db02dbbfe5-Bussard, David]; Cogliano, Vincent

[/o=ExchangeLabs/ou=Exchange Administrative Group

 $(FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano,\ Vincent];\ Rogers,\ John\ M.$

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=9d2a5d5b6a71487cb4373cfcea7bb01b-Rogers, John M.]; Jones, Samantha

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samantha]; Hagerthey, Scot

[/o=ExchangeLabs/ou=Exchange Administrative Group]

(FYDIBOHF23SPDLT)/cn=Recipients/cn=40321ee06f2848b89f820d4a230cfde7-Hagerthey, Scot]; Birchfield, Norman

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=c910f2fd28414e819b6afe6dda525e9f-Birchfield, Norman]; Morozov, Viktor

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=03cc9abb639c453fabc2bbb3e4617228-Morozov, Viktor]; Makris, Susan

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7654051d8d1240a39dfa9463c9b0b7e5-Makris, Susan]; Walton, Barb

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=e8ebb13afaf343b28b3e8552447e86ba-Walton, Barbara]

Subject: FYI: OECD: survey on the regulatory need and use of TG 415 and TG 416 and replacement with Extended One Gene

Repro study, cross EPA meeting on Monday (Aug 29)

Attachments: SURVEY OF COUNTRIES REGULATORY NEEDS FOR TG 415-TG 416.docx; Response to Survey on Proposed Deletion of

TG 415 & 416 Call in number 866-299-3188 Code 703-347-0448.ics

Hello evervone:

Deliberative Process / Ex. 5

Thanks! Lynn

Lynn Flowers, PhD, DABT Office of Science Policy US EPA Washington, DC 202-564-6293

From: Hall, Wanda

Sent: Monday, June 27, 2016 11:30 AM

To: Chen, Tracy < Tracy.Chen@fda.hhs.gov >; 'Martha Moore' < MMMoore@ramboll.com >; 'caseywm@niehs.nih.gov' < caseywm@niehs.nih.gov >; Tim Springer (tspringer@eag.com) < tspringer@eag.com >; 'mjaber@eag.com >; 'mjaber@eag.com' < mjaber@eag.com >; Jay West < Jay West@americanchemistry.com >; kamala.pant@bioreliance.com

Cc: Paris, Michael (NIH/NIEHS) [C] < paris@niehs.nih.gov >; 'Strickland, Judy (NIH/NIEHS) [C]' < strickl2@niehs.nih.gov > Subject: FW: OECD, WNT: Launching a survey on the regulatory need and use of TG 415 and TG 416, Deadline for responses 24 AUGUST 2016

Dear Colleagues,

Deliberative Process / Ex. 5

Thank you for your continued support to the WNT, Wanda

Wanda J. Hall

US National Coordinator for OECD Test Guidelines
US EPA NAFTA Secretariat for Office of Pesticide Programs
US Environmental Protection Agency
Field and External Affairs Division
Office of Pesticide Programs
Office of Chemical Safety and Pollution Prevention
1200 Pennsylvania Ave, NW (7506P)
Washington, DC 20460
hall.wanda@epa.gov

Office Tel: 703-347-0448
Mobile: Personal Phone / Ex. 6

Fax: 703-305-6244

Courier Address: Potomac Yards South 2777 Crystal Drive (Room 8825) Arlington, VA 22202

Appointment

Hall, Wanda [Hall.Wanda@epa.gov] From:

To: Lowit, Anna [Lowit.Anna@epa.gov]; Mendez, Elizabeth [Mendez.Elizabeth@epa.gov]; Reaves, Elissa

[Reaves.Elissa@epa.gov]; Blankinship, Amy [Blankinship.Amy@epa.gov]; Garber, Kristina [Garber.Kristina@epa.gov];

Noyes, Pamela [Noyes.Pamela@epa.gov]; Schappelle, Seema [Schappelle.Seema@epa.gov]; Barone, Stan

[Barone.Stan@epa.gov]; Benson, Amy [Benson.Amy@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Flowers, Lynn

[Flowers.Lynn@epa.gov]; devitom@niehs.nih.gov; caseywm@niehs.nih.gov; Panger, Melissa

[Panger.Melissa@epa.gov]

Subject: Response to Survey on Proposed Deletion of TG 415 & 416 Call in number: Teleconference Line / Ex. 6

Attachments: 08-16-2016 SURVEY OF COUNTRIES REGULATORY NEEDS FOR TG 415-TG 416_LIM.docx

Location: DCRoomPYS7100/Potomac-Yard-One

Start: 8/29/2016 3:00:00 PM End: 8/29/2016 4:00:00 PM

Show Time As: Busy

Recurrence:

Colleagues,

Deliberative Process / Ex. 5

From: Bucher, John (NIH/NIEHS) [E] [bucher@niehs.nih.gov]

Sent: 7/17/2016 4:27:54 PM

To: dkrewski@uottawa.ca [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=ef67228b71b04e6eb857fc18e459b5bf-dkrewski@uo]; Rusyn, Ivan [IRusyn@cvm.tamu.edu]; Robert Baan [BaanR@visitors.iarc.fr]; Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano,

Vincent]; Kaylock, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=eebac67f01094409a7fdaa955a837884-Kavlock, Robert]

CC: straif@iarc.fr; cportier@mac.com

Subject: Re: Tumour-site Concordance and Mechanisms of Carcinogenesis

Robert and all involved,

Thanks for all the efforts at pulling this together. I had a few additional comments to those of Ivan on the consensus statements for your consideration.

Best, John

Deliberative Process / Ex. 5

From: Daniel Krewski <dkrewski@uottawa.ca>

Date: Saturday, July 16, 2016 at 5:37 PM

To: "Rusyn, Ivan" < Rusyn@cvm.tamu.edu>, Robert Baan < Baan R@visitors.iarc.fr>,

"Cogliano.Vincent@epamail.epa.gov" <Cogliano.Vincent@epamail.epa.gov>, "kavlock.robert@epa.gov"

<kavlock.robert@epa.gov>, "John R. Bucher" <bucher@niehs.nih.gov>

Cc: "straif@iarc.fr" <straif@iarc.fr>, Christopher Portier < Personal Matters / Ex. 6 ≥

Subject: RE: Tumour-site Concordance and Mechanisms of Carcinogenesis

Thanks for your positive comments, Ivan, and for your specific comments on the draft consensus statement.

Although Robert will be coordinating the response to all comments by the Workshop Participants, I've offered a few perspectives on some of your comments below (a pleasant way to pass the time sitting in Montreal airport on my way home from Lyon) . . .

From: Rusyn, Ivan [mailto:IRusyn@cvm.tamu.edu]

Sent: July-16-16 12:19 PM

To: Robert Baan < Baan R@visitors.iarc.fr>; Cogliano.Vincent@epamail.epa.gov; kavlock.robert@epa.gov; Daniel Krewski

<dkrewski@uottawa.ca>; 'bucher@niehs.nih.gov' <bucher@niehs.nih.gov>

Cc: straif@iarc.fr; Personal Matters / Ex. 6

Subject: RE: Tumour-site Concordance and Mechanisms of Carcinogenesis

Dear Robert,

Great job. Congratulations!

Deliberative Process / Ex. 5

Thank you!

Ivan

| From: Robert Baan [mailto:BaanR@visitors.iarc.fr] |
|---|
| Sent: Friday, July 15, 2016 3:52 PM |
| To: banks@icgeb.org; frederick.beland@fda.hhs.gov; Personal Matters / Ex. 6 boslandm@uic.edu; bucher@niehs.nih.gov; |
| caldwell.jane@epa.gov; Cogliano.Vincent@epamail.epa.gov; demarini.david@epa.gov; bice.fubini@unito.it; |
| bdgold@pitt.edu; hecht002@umn.edu; k.hemminki@dkfz.de; mark.hill@rob.ox.ac.uk; Personal Matters / Ex. 6 ; |
| Agnes_Kane@Brown.edu; kavlock.robert@epa.gov; dkrewski@uottawa.ca; lambert@oncology.wisc.edu; |
| Personal Matters / Ex. 6 Personal Matters / Ex. 6 jr 332@georgetown.edu; martynts@uclink4.berkeley.edu; |
| lstayner@uic.edu; ullrich@rerf.or.jp; p.vineis@imperial.ac.uk; waalkes@niehs.nih.gov; lzeise@oehha.ca.gov; |
| Bernard.Stewart@sesiahs.health.nsw.gov.au; Personal Matters / Ex. 6 ; Personal Matters / Ex. 6 zoughoolm@ksau- |
| hs.edu.sa; Personal Matters / Ex. 6 ilittle@uottawa.ca; bmilton@risksciences.com; malzough@uottawa.ca; |
| Nicholas.Birkett@uottawa.ca; Harri.Vainio@hsc.edu.kw; Rusyn, Ivan < IRusyn@cvm.tamu.edu>; Personal Matters / Ex. 6 |
| Cc: straif@iarc.fr; Personal Matters / Ex. 6 cphra@uottawa.ca; bullrich@utmb.edu; Personal Matters / Ex. 6 ; |
| workshops100+@iarc.fr |
| Subject: Tumour-site Concordance and Mechanisms of Carcinogenesis |
| Dear colleagues, |
| It has been a long time since we had contact; I hope you are doing fine. |
| |
| |
| |
| |
| |
| |
| |
| |
| PBI / Ex. 4 |

I hope to hear from you, wishing you pleasant holidays.

With my best regards,

Robert

From: Burke, Thomas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=39FFC3DD34EA495B9A31E61B778FBBEC-BURKE, THOM]

Sent: 11/12/2015 10:15:01 PM

To: Bahadori, Tina [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7da7967dcafb4c5bbc39c666fee31ec3-Bahadori, Tina]; Kavlock, Robert

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=eebac67f01094409a7fdaa955a837884-Kavlock, Robert]; Deener, Kathleen

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b9a2ff1c086249ea8f6414afde8a5e54-Deener, Kathleen]; Cogliano, Vincent

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]

Subject: Fwd: Summary

FYI

Thomas A. Burke, PhD, MPH
Deputy Assistant Administrator
EPA Science Advisor
Office of Research and Development
Personal Matters / Ex. 6
burke. thomas@epa.gov

Begin forwarded message:

From: "Jones, Jim" < Jones.Jim@epa.gov > Date: November 12, 2015 at 7:57:36 AM EST To: "Burke, Thomas" < Burke.Thomas@epa.gov >

Subject: Fwd: Summary

Tom, FYI. Jim

Sent from my iPhone

Begin forwarded message:

From: "Housenger, Jack" < Housenger. Jack@epa.gov>

Date: November 12, 2015 at 7:30:59 AM EST

To: "Jones, Jim" < Jones. Jim@epa.gov>

Subject: Summary

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Sent from my iPhone

From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]

Sent: 8/31/2016 1:38:44 PM

To: Ross, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=98359cd1f66f46ec91d327e99a3c6909-Ross, Mary]

Subject: Re: Mercury IG report: input needed from IRIS

Who is going to do the updates? Fewer people than now do a never-ending IRIS assessment with eight intermediate drafts.

Deliberative Process / Ex. 5

From: Cogliano, Vincent

Sent: Tuesday, August 30, 2016 11:54 PM

To: Perovich, Gina < Perovich.Gina@epa.gov">Perovich, Gina Perovich, Gina Perovich, Gina@epa.gov; Rieth, Susan Rieth, Susan Rieth, Susan Rieth.Susan@epa.gov); Soto, Vicki Soto.Vicki@epa.gov);

Ross, Mary <Ross.Mary@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; D'Amico, Louis

<DAmico.Louis@epa.gov>

Cc: Slimak, Michael <<u>Slimak.Michael@epa.gov</u>>
Subject: Mercury IG report: input needed from IRIS

Hello everyone—Passing this along for action by next week. See Tom Burke's message.

Deliberative Process / Ex. 5

Perhaps a topic for the next IRIS Mgmt Council? Or is the course of action clear?

Vince

Begin forwarded message:

From: "Burke, Thomas" <Burke. Thomas@epa.gov>

Date: August 30, 2016 at 17:45:06 EDT

To: "Blackburn, Elizabeth" < Blackburn. Elizabeth@epa.gov >, "Corona, Elizabeth"

< Corona. Elizabeth@epa.gov>, "Deener, Kathleen" < Deener. Kathleen@epa.gov>, "Cogliano, Vincent"

<cogliano.vincent@epa.gov>

Cc: "Slimak, Michael" < Slimak.Michael@epa.gov>

Subject: Fwd: Discussion Document for OIG Mercury in Fish Assignment

I want to make we respond. The ORD recommendation is straight forward, just want to check in with others on getting our comments in.

Tom

Sent from my iPhone

Begin forwarded message:

From: "Ross, Johnny" < Ross. Johnny@epa.gov>

Date: August 26, 2016 at 12:20:13 PM EDT

To: "Shapiro, Mike" <<u>Shapiro.Mike@epa.gov</u>>, "Wathen, John" <<u>Wathen.John@epa.gov</u>>, "Larimer, Lisa" <<u>Larimer.Lisa@epa.gov</u>>, "Cogliano, Vincent" <<u>cogliano.vincent@epa.gov</u>>, "Perovich, Gina" <<u>Perovich.Gina@epa.gov</u>>, "Burke, Thomas" <<u>Burke.Thomas@epa.gov</u>>

Cc: "Nishida, Jane" < Nishida. Jane@epa.gov >, "Chase, JoAnn" < Chase. JoAnn@epa.gov >,

"Walker, Khadija" <<u>walker.khadija@epa.gov</u>>, "Butler, Kathlene" <<u>Butler.Kathlene@epa.gov</u>>, "HAMANN, JULIE" <Hamann.Julie@epa.gov>, "Snyder, Gerry" <Snyder.Gerry@epa.gov>

Subject: Discussion Document for OIG Mercury in Fish Assignment

Attached is the Discussion Document for the OIG's Mercury in Fish assignment for your review and comment. Please respond to the document with comments by September 12, 2016. We look forward to your insights and making this a meaningful report. If your office has any questions or would like to meet with our review team, please contact me at your earliest convenience. We look forward to hearing from you soon.

Johnny D. Ross

Program Analyst

EPA/OIG/OPE

61 Forsyth St. Suite 12T24

Atlanta, GA 30303

404 562-9863



From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]

Sent: 11/13/2017 7:27:50 PM

To: Stilp, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=eb174399b2084a7c87d4d584e6f7fbca-Stilp, Mark]

CC: Saint, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=b85c2ad71ca8454f86716fd3eb8fc888-Saint, Christopher]

Subject: RE: Litigation Question, FOIA document release

Hi Mark-

Attorney Client / Ex. 5

Attorney Client / Ex. 5

Attorney Client / Ex. 5

Vince

From: Stilp, Mark

Sent: Wednesday, 8 November, 2017 15:50

To: Cogliano, Vincent <cogliano.vincent@epa.gov>

Cc: Saint, Chris <Saint.Chris@epa.gov>

Subject: Litigation Question, FOIA document release

Hi Vince-

Attorney Client / Ex. 5

Thanks for all your help and time over the past week.

-Mark Stilp

Mark Stilp | Attorney-Advisor | Office of General Counsel | U.S. Environmental Protection Agency | 1200 Pennsylvania Ave. NW | Washington, DC 20460 | mail code: 2377A | office: 202.564.4845 | cell | Personal Phone / Ex. 6

Message

From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]

Sent: 9/29/2016 1:43:23 AM

To: Ross, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=98359cd1f66f46ec91d327e99a3c6909-Ross, Mary]

Subject: Re: VINCE -- need to check with you in the morning -- : Contingency Planning -- Review/Update of Excepted

Personnel List - DUE DATE - Noon 9/29

Personal email: Personal Email / Ex. 6

Personal mobile is correct.

On Sep 28, 2016, at 21:24, Ross, Mary <Ross.Mary@epa.gov> wrote:

Hi Vince. Here's the info they have for you now. Is it correct? They're looking for an answer by noon tomorrow and my morning is rather crammed, so I'm sending this reminder now. Thanks.

| Cogliano, Vincent | Division Director, IRIS | 1 | 1 | assist in orderly shutdown of | (C) | |
|-------------------|----------------------------|---|---|-------------------------------|--------------------------|--|
| | | | | center activities | Personal Matters / Ex. 6 | |

From: Ross, Mary

Sent: Wednesday, September 28, 2016 10:01 AM

To: Slimak, Michael <Slimak.Michael@epa.gov>; Bussard, David <Bussard.David@epa.gov>; Cogliano, Vincent

<cogliano.vincent@epa.gov>; Gatchett, Annette <Gatchett.Annette@epa.gov>; Hagerthey, Scot

<Hagerthey.Scot@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov>; Saint, Chris <Saint.Chris@epa.gov>; Troyer,

Michael <<u>Troyer.Michael@epa.gov</u>>; Vandenberg, John <<u>Vandenberg.John@epa.gov</u>>; Walsh, Debra

<<u>Walsh.Debra@epa.gov</u>>

Subject: FW: Contingency Planning -- Review/Update of Excepted Personnel List - DUE DATE - Noon 9/29

Hi everyone – FYI, a little planning for the FY transition. As they say, a shutdown is not anticipated, but just in case, we're updating the excepted personnel list.

This is an easy update and I can do it, but would like the divisions to check:

- personal email and phone numbers are correct?
- Vince, do you have a personal email address to add?
- Mike, I'll need your info, can get it when you arrive. I think I'll suggest retaining both of us on the list, so I can be a contact in the PY area.

From: Vaughan, Pat

Sent: Wednesday, September 28, 2016 9:48 AM

To: ORD-Mgmt-Council < ORDMgmtCouncil@epa.gov>; ORD-POS-Directors < ORDPOSDirectors@epa.gov> **Cc:** Robbins, Chris < Robbins, Chris@epa.gov>; Steenbock, John < Steenbock, John@epa.gov>; Mayes, Desmond

<<u>Mayes.Desmond@epa.gov</u>>; Blackburn, Elizabeth <<u>Blackburn.Elizabeth@epa.gov</u>>

Subject: FW: Contingency Planning -- Review/Update of Excepted Personnel List - DUE DATE - Noon 9/29

All.

We have been asked by the agency to update our latest excepted/shutdown list (attached). As you will see from the note below, a lapse in funding is not expected, but it is important to be prepared. We will need to have this updated and ready to submit to the agency if/when requested (which could be as early as this Friday morning).

Please make any changes to the section for your LCO in red and send the revised copy to me **by noon tomorrow**, **September 29**. I will merge them together and prepare a final list.

If you have any questions, please let me know.

Pat Vaughan
Director, Human Resources Division
ORD/Office of Administrative and Research Support
919-541-4912
Personal Matters / Ex. 6 (cell)
OARS Website

From: Robbins, Chris

Sent: Wednesday, September 28, 2016 9:28 AM

To: Steenbock, John <<u>Steenbock.John@epa.gov</u>>; Mayes, Desmond <<u>Mayes.Desmond@epa.gov</u>>; Vaughan, Pat <<u>Vaughan.Pat@epa.gov</u>>

Cc: Blackburn, Elizabeth <<u>Blackburn.Elizabeth@epa.gov</u>>; Kavlock, Robert <<u>Kavlock.Robert@epa.gov</u>>; Burke, Thomas <<u>Burke.Thomas@epa.gov</u>>

Subject: Fwd: Contingency Planning -- Review/Update of Excepted Personnel List

Hi folks

Pls get this out to Lco's and work with them to update. Thx!

Sent from my iPhone

Begin forwarded message:

From: "Showman, John" <Showman.John@epa.gov>

To: "ARA" <<u>ARA@epa.gov</u>>, "DRA" <<u>DRA@epa.gov</u>>, "DAA" <<u>DAA@epa.gov</u>>

Cc: "Fritz, Matthew" < Fritz.Matthew@epa.gov >, "Badalamente, Mark" < Badalamente.Mark@epa.gov >, "Salgado, Omayra" < Salgado, Omayra@epa.gov >, "Morales, Oscar" < Morales.Oscar@epa.gov >, "Young, Brenda" < young.brenda@epa.gov >, "Maher, Karen" < Maher.Karen@epa.gov >, "Cunningham, Dennis" < Cunningham.Dennis@epa.gov >, "Blackburn, Elizabeth" < Blackburn.Elizabeth@epa.gov >, "Simon, Nigel"

<<u>Simon.Nigel@epa.gov</u>>, "Fontaine, Tim" <<u>Fontaine.Tim@epa.gov</u>>, "Allen, Reginald"

<a>Allen.Reginald@epa.gov>, "Packard, Elise" <Packard.Elise@epa.gov>, "Osborne, Howard"

<Osborne.Howard@epa.gov>, "Hitchens, Lynnann" <hitchens.lynnann@epa.gov>, "Cooper, Marian"

<<u>Cooper.Marian@epa.gov</u>>, "Flynn, Mike" <<u>Flynn.Mike@epa.gov</u>>, "Meiburg, Stan"

<Meiburg.Stan@epa.gov>, "Hardy, Michael" <Hardy.Michael@epa.gov>

Subject: Contingency Planning -- Review/Update of Excepted Personnel List

As you know annual funding for the government expires on Friday, September 30th. While the Administration strongly believes that a lapse in funding should not occur and there is enough time for Congress to prevent a lapse in appropriations, we need to be prepared in the event we are faced with quickly

implementing our contingency plan. Therefore, prudent management requires that all program and regional offices start reviewing their last list of shutdown and excepted personnel (from September or December 2015) to determine what updates would be necessary. Your last list is attached. Updates <u>could</u> be requested as early as Friday morning.

We will continue to provide updates based on information received from OMB. Thanks.

John L Showman III, Acting Principal Deputy Assistant Administrator Office of Administration and Resources Management 202-564-5341

<ORD Master Shutdown List (incl LCO pgs) December 2015.xlsx>

Message

From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]

Sent: 7/31/2015 7:51:23 PM

To: Jones, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=eac77fe3b20c4667b8c534c90c15a830-Jones, Samanthal

Subject: FW: Silbergeld review of arsenic

Attachments: cover letter.docx; As HI Diabetes 012715 (2) eks review 3.15.docx

From: Ellen Silbergeld [mailto:esilber2@jhu.edu]

Sent: Friday, March 13, 2015 4:35 PM

To: Cogliano, Vincent

Subject: RE: Penelope Fenner-Crisp -- Former Pesticides Official Questions IRIS' Outdated Pesticide Assessments

I submitted my comments as requested; here is a copy for you

Ellen K Silbergeld, PhD Professor, Environmental Health Sciences Johns Hopkins Bloomberg School of Public Health 615 North Wolfe Street, Rm E6644 Baltimore MD 21205 USA

tel: 410 955 8678 fax: 443 287 6414

PLEASE NOTE: IF YOU DO NOT RECEIVE A PROMPT RESPONSE FROM ME TO AN EMAIL, PLEASE RESEND IT AS WE ARE HAVING ISSUES WITH OUR EMAIL SYSTEM. IF YOU STILL DO NOT RECEIVE A RESPONSE, YOU MAY HAVE TO CALL ME BY PHONE.

From: Cogliano, Vincent [mailto:cogliano.vincent@epa.gov]

Sent: Friday, March 13, 2015 4:29 PM

To: Ellen Silbergeld; Daniele Mandrioli (Personal Matters / Ex. 6)

Subject: RE: Penelope Fenner-Crisp -- Former Pesticides Official Questions IRIS' Outdated Pesticide Assessments

Thanks for sharing these messages, Ellen. The pesticides-on-IRIS story goes back several decades. Someday we'll fix all the messes that were left for us ... though getting closer to systematic review AND having a productive program are more important.

I like to theme of the Vienna meeting – filtering information overload. I can really identify with that, given the 1000+page documents of IRIS past. Unfortunately, we don't have much chance for discretionary international travel.

I just saw the Collegium's response to the bad-luck paper. Well done, and I'm happy that you took the lead to get this out.

Have you prepared written comments on that arsenic section? I've seen most of the other comments, and it's unfortunate that some were less thorough than others. The most knowledgeable comments literally made my head spin (really – I woke up with vertigo the next morning for the first time in 10 years). I'm waiting to see yours, as you've told me about systematic review concerns that the others haven't raised.

Best regards,

```
From: Ellen Silbergeld [mailto:esilber2@jhu.edu]
Sent: Thursday, March 12, 2015 11:43 AM
```

To: Daniele Mandrioli (Personal Matters / Ex. 6 ; Cogliano, Vincent

Subject: Fwd: Penelope Fenner-Crisp -- Former Pesticides Official Questions IRIS' Outdated Pesticide Assessments

Why we need systematic methods as soon as possible. Come to Vienna

Sent from my iPhone

Begin forwarded message:

```
From: "Huff, James (NIH/NIEHS) [G]" < huff1@niehs.nih.gov >

Date: March 12, 2015 at 10:59:45 AM EDT

To: Myra Karstadt < Personal Matters / Ex. 6 to Cc: Jane Caldwell < Caldwell Jane@epamail.epa.gov >, ronald melnick < Personal Matters / Ex. 6 >, "jennifer sass [NRDC]" < jsass@nrdc.org >, Ellen Silbergeld < esilber2@jhu.edu >, "fiorella belpoggi" < belpoggif@ramazzini.it >
```

Subject: Re: Penelope Fenner-Crisp -- Former Pesticides Official Questions IRIS' Outdated Pesticide Assessments

M-

Fully agree — she was industry when at EPA for sure. Now testifies in cases for industry, oh well we know lots of people like her who enjoyed high paying gov jibs, retired with terrific benefits and than show their true anti-publi health character. Too many in fact from NTP as well. Disgusting

```
From: myra karstadt Personal Matters / Ex. 6 t Personal Matters / Ex. 6 Poate: Wednesday, March 11, 2015 at 19:09

To: james huff huff1@niehs.nih.gov mailto:huff1@niehs.nih.gov Cc: Jane Caldwell

Caldwell Jane@epamail.epa.gov mailto:Caldwell Jane@epamail.epa.gov nonald melnick

Personal Matters / Ex. 6 mailto: Personal Matters / Ex. 6 Poet infante

Personal Matters / Ex. 6 Personal Matters / Ex. 6 Poet infante

Personal Matters / Ex. 6 Personal Matters / Ex. 6 Poet infante

Signs @nrdc.org mailto:jsass@nrdc.org Personal Matters / Ex. 6 Poet infante
```

Subject: Re: Penelope Fenner-Crisp -- Former Pesticides Official Questions IRIS' Outdated Pesticide Assessments

penny fenner-crisp is not a pro-public health person. last time i noticed, she was working for ilsi, the industry-oriented group that houses the risk science institute. i remember her being not at all supportive of public health priorities when she was at epa. wonder who she's consulting for on the pesticides-iris issue. incidentally, the combination of penny and olden likely merits some concern.

On Mar 11, 2015, at 4:39 PM, Huff, James (NIH/NIEHS) [G] huff1@niehs.nih.gov wrote:

Wednesday, March 11, 2015 RISK POLICY REPORT - 03/10/2015

Former Pesticides Official Questions IRIS' Outdated Pesticide Assessments A retired EPA pesticides official is pressing the agency to address the more than 100 pesticides included in the agency's Integrated Risk Information System (IRIS) toxicity assessment database for environmental chemicals, arguing that these outdated, 30-year-old assessments undermine the influential database's authority.

"In my view, it is a big problem for IRIS and [EPA's National Center for Environmental Assessment (NCEA)] and a significant impediment to the reestablishment of IRIS as a credible repository of Agency-generated human health guidance," Penelope Fenner-Crisp, a former EPA pesticides official writes in a Dec. 15 letter to NCEA Director Ken Olden, and recently released in IRIS' electronic docket. Relevant documents are available on InsideEPA.com. (Doc. ID: 179497)

EPA's IRIS database provides toxicity information agency-wide about chemicals and other factors in the environment that may cause adverse health effects, and many risk management decisions are based on the assessments. The database is publicly available on the internet, and many state agencies and agencies in other countries consult it.

The IRIS program has long held the goal of updating its existing assessments at least once a decade. However, that goal is rarely met, with the program in recent years completing just a handful of assessments per year. In fiscal year 2014, the agency did not publish any final IRIS assessments. In a 2008 review, the Government Accountability Office declared the program so slow-moving as to be nearly obsolete.

Fenner-Crisp, who at various public meetings has questioned the use of a separately staffed IRIS program rather than a consensus committee of agency-wide risk assessors, as in the early days of the database, writes, "over the time frame during which the IRIS process was a collaborative one (1987-1995), 462 chemical entries were uploaded onto IRIS. In the nearly 20 years since IRIS was taken over by NCEA, only 95 additional chemical entries have been uploaded onto IRIS." Olden, who was brought into EPA to turn around the troubled program two years ago, announced in December at the annual meeting of the Society for Risk Analysis in Denver that he intends to remove some 140 IRIS assessments from the database because they are outdated. And he indicated plans to update about 350 other assessments in the database (Risk Policy Report, Dec. 15).

However, those plans have yet to come to fruition. Fenner-Crisp, who questioned Olden about the status of the outdated pesticides assessments in the IRIS database at the Denver meeting, sent Olden her analysis of the number of outdated IRIS assessments in the database. According to her review, "nearly 200 of the 558 entries on IRIS are currently-registered or recently-canceled pesticides," Fenner-Crisp writes.

In her analysis, Fenner-Crisp reviews this group of 193 pesticides and compares the cancer and noncancer toxicity estimates in the IRIS database with the toxicity estimates EPA's Office of Pesticide Programs (OPP) has generated for the same chemicals since the IRIS values were calculated in the 1980s. She notes that many of the values are different and argues this undermines IRIS' credibility.

"Of the nearly 200 chemicals, almost 90 percent of the IRIS entries for these substances are incorrect, either for the [non-cancer reference dose (RfD)] or the cancer call or both," Fenner-Crisp writes. "This is the 800-pound elephant in the room. This problem needs to be corrected, swiftly and thoroughly, if there is any hope of fully restoring credibility to IRIS." Fenner-Crisp writes that anyone -- inside or outside the agency -- who has used the IRIS pesticide values rather than the updated OPP values has been using outdated information "for at least 20 years". And she writes that "[a]t least one EPA program office (Superfund) is trapped into using the wrong numbers for pesticides as a matter of policy," pointing to Superfund's Risk Assessment Guidance for Superfund, where IRIS is described as "superseding" all other information sources.

An agency source says that IRIS leaders are working to get the outdated assessments removed from IRIS, but bureaucratic delays are slowing action. The main delay, the source says, is that in the process of reviewing and determining which pesticides are outdated and obtaining agreement within the agency to remove the assessments, "somebody discovered that there's another set [of

chemicals] that [NCEA] also doesn't have responsibility for." The source was unsure, but thought this other group of chemicals also falls within OPP's authority. The source adds that the intent is to remove both sets of chemicals from IRIS together.

Fenner-Crisp provides Olden with the history of the outdated pesticide values on the IRIS database. When the IRIS program began in the early 1980s, the agency's water and pesticides offices were seeking to gain consensus on toxicity values for chemicals found in drinking water systems, with drinking water utilities asking for EPA advice on treatment, she explains. She notes that she and two colleagues generated many of these values before the effort grew into a larger Refence Dose Workgroup in 1985. This group continued generating IRIS toxicity values until the separate IRIS program, with sole responsibility for creating the IRIS assessments, was created in 1995, Fenner-Crisp writes.

"So, what does this say about the credibility of the IRIS entries for pesticides? Most of the IRIS entries uploaded between 1987 and 1989 were derived by Drs. Dourson, Engler and myself, later verified by the RfD Workgroup. That means these values are ~30 years old--way out of date and frozen in time."

Fenner-Crisp adds that "[a]nother very significant change occurred at the 1995 time point, which is not widely remembered and rarely acknowledged. The NCEA-led Agency consensus activities on pesticides ended. The responsibility for the development of health-based values reverted to the [OPP]. Maintenance and updating of IRIS values by NCEA for pesticides ceased, with minor exceptions. If the substance is used primarily for purposes other than as a pesticide, NCEA has retained the responsibility for updating the assessment. In these instances, OPP is consulted and the outcome of the assessment generally represents a consensus opinion."

One example of this unusual instance is the long ongoing IRIS assessment of the chemical ethylene oxide, which has both pesticidal and industrial uses. Because of the dual uses of the chemical, IRIS retains the authority to assess it, an agency source said during the last peer review of the draft assessment (Risk Policy Report, Nov. 25).

In her analysis, Fenner-Crisp goes through the 193 pesticide compounds in the IRIS database and compares the toxicity estimates with any newer estimates that OPP has generated. She notes that of the 167 IRIS pesticide entries that are not up to date, "For 27 entries, the [non-cancer toxicity estimates, or RfDs] match, but the cancer calls do not . . . For 19 entries, the RfDs do not match, but the cancer calls do . . . For 121 entries, neither the RfD nor the cancer call match . . . " -- Maria Hegstad

Message

From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]

Sent: 12/8/2016 2:53:48 PM

To: Glenn, Barbara [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=7a2dc9210d2d4d02a623b33f87f49436-Glenn, Barbara]

Subject: FW: draft epi framework/OPP

Attachments: Revised Epi-Incident Framework_Draft_12-5-16-clean.docx; ATT00001.htm

From: Lavoie, Emma

Sent: Wednesday, December 07, 2016 4:47 PM

To: Vandenberg, John < Vandenberg. John@epa.gov>; Bussard, David < Bussard. David@epa.gov>; Cogliano, Vincent < cogliano.vincent@epa.gov>

Cc: Ross, Mary <Ross.Mary@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Slimak, Michael <Slimak.Michael@epa.gov>; Perovich, Gina <Perovich.Gina@epa.gov> **Subject:** FW: draft epi framework/OPP

Hi John, Dave, Vince,

I spoke to Lynn F this morning for some clarity on this. Since the deadline for comments is Dec 19th – could you identify epidemiology reviewers for the OPP epi framework draft – attached? The names Molini Patel and Barbara Glenn have been suggested as possible reviewers. Please let me know by Friday who can review. The meeting in Lynn's message is Dec 14. Having input from your reviewers on any items that would be contradictory or an issue for the IRIS review handbook by the morning of the 14th would be really helpful.

Deliberative Process / Ex. 5

Please call me if you need to discuss...thanks.

-Emma

Emma T. Lavoie, PhD Tel: 703-347-0328

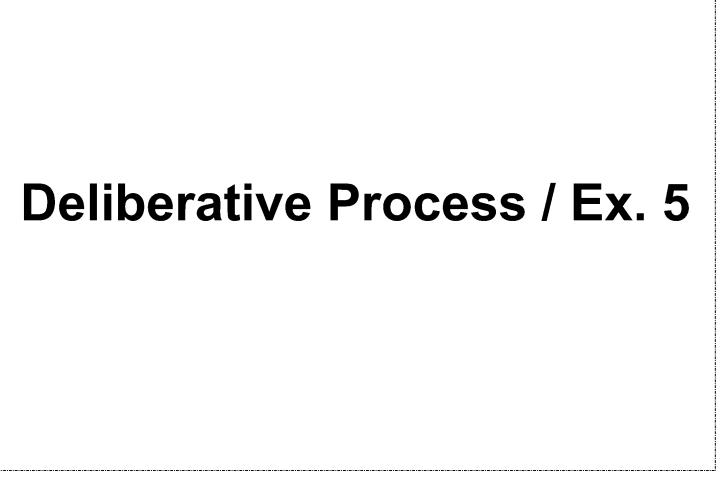
From: Flowers, Lynn

Sent: Tuesday, December 06, 2016 3:37 PM **To:** Lavoie, Emma < <u>Lavoie</u>. Emma@epa.gov>

Cc: Slimak, Michael <<u>Slimak.Michael@epa.gov</u>>; Cogliano, Vincent <<u>cogliano.vincent@epa.gov</u>>; Ross, Mary <<u>Ross.Mary@epa.gov</u>>; Perovich, Gina <<u>Perovich.Gina@epa.gov</u>>; D'Amico, Louis <<u>DAmico.Louis@epa.gov</u>>; McQueen, Jacqueline <<u>McQueen.Jacqueline@epa.gov</u>>; Gwinn, Maureen <<u>gwinn.maureen@epa.gov</u>>; Vandenberg, John <<u>Vandenberg.John@epa.gov</u>>; Bussard, David <<u>Bussard.David@epa.gov</u>>

Subject: Fwd: draft epi framework/OPP

Hi Emma and everyone: I am again reaching out to the larger management group re: OPPs draft epi framework. This was discussed briefly at the end of the meeting with Matt Fritz last week but I expect not everyone heard.



I look forward to your reply.

Sent from my iPhone

Begin forwarded message:

From: < Personal Matters / Ex. 6 >

Date: December 6, 2016 at 3:11:37 PM EST

To: <flowers.lynn@epa.gov>

Subject: draft epi framework/OPP

Message

From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]

Sent: 6/15/2017 4:49:01 PM

To: Lowit, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=1d3428a2c0b84d5099124a0460babd53-Anna B. Lowit]

CC: Nguyen, Khue [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=53463f4f956d4772a6ada2f68debfcb8-Nguyen, Khue]

Subject: Re: Reuters story on glyphosate and additional information

Deliberative Process / Ex. 5

On Jun 15, 2017, at 12:41, Lowit, Anna <<u>Lowit.Anna@epa.gov</u>> wrote:

Thanks for the call this morning & the information.

Just a quick question,

Deliberative Process / Ex. 5

Anna

Anna B. Lowit, Ph.D.

Senior Science Advisor Immediate Office Office of Pesticide Programs, USEPA

W: 703-308-4135
C: Personal Phone / Ex. 6

From: Cogliano, Vincent

Sent: Thursday, June 15, 2017 11:55 AM

To: Lowit, Anna <<u>Lowit.Anna@epa.gov</u>>; Nguyen, Khue <<u>Nguyen.Khue@epa.gov</u>>

Subject: Reuters story on glyphosate and additional information

Hello Anna—Yesterday after work I received this link (below) to a story in Reuters regarding glyphosate, plus two attached files that are mentioned in the story. I know that OPP would want to be aware of this ... Best regards, Vince

http://www.cnbc.com/2017/06/14/reuters-america-special-report-cancer-agency-left-in-the-dark-over-glyphosate-evidence.html

From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]

Sent: 7/21/2016 1:21:03 PM

To: Bucher, John (NIH/NIEHS) [E] [bucher@niehs.nih.gov]; dkrewski@uottawa.ca [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef67228b71b04e6eb857fc18e459b5bf-dkrewski@uo];

Rusyn, Ivan [IRusyn@cvm.tamu.edu]; Robert Baan [BaanR@visitors.iarc.fr]; Kavlock, Robert

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=eebac67f01094409a7fdaa955a837884-Kavlock, Robert]

CC: straif@iarc.fr; cportier@mac.com

BCC: Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]

Subject: RE: Tumour-site Concordance and Mechanisms of Carcinogenesis

Hello everyone—Thank you for the comments. My suggestions are interspersed below in green. I like Bob K's suggestion for #10, too, but I had already started on a previous message from the thread ... Best regards to all—Vincent

From: Bucher, John (NIH/NIEHS) [E] [mailto:bucher@niehs.nih.gov]

Sent: Sunday, July 17, 2016 12:28 PM

To: dkrewski@uottawa.ca; Rusyn, Ivan <IRusyn@cvm.tamu.edu>; Robert Baan <BaanR@visitors.iarc.fr>; Cogliano,

Vincent <cogliano.vincent@epa.gov>; Kavlock, Robert <Kavlock.Robert@epa.gov>

Cc: straif@iarc.fr; Personal Email / Ex. 6

Subject: Re: Tumour-site Concordance and Mechanisms of Carcinogenesis

Robert and all involved.

Thanks for all the efforts at pulling this together. I had a few additional comments to those of Ivan on the consensus statements for your consideration.

Best, John

PBI / Ex. 4

Deliberative Process / Ex. 5

From: Daniel Krewski < dkrewski@uottawa.ca > Date: Saturday, July 16, 2016 at 5:37 PM

To: "Rusyn, Ivan" <IRusyn@cvm.tamu.edu>, Robert Baan <BaanR@visitors.iarc.fr>,

"Cogliano.Vincent@epamail.epa.gov" <Cogliano.Vincent@epamail.epa.gov>, "kavlock.robert@epa.gov"

<a href="mailto:, "John R. Bucher" < bucher@niehs.nih.gov>

Cc: "straif@iarc.fr" < straif@iarc.fr>, Christopher Portier < cportier@mac.com> **Subject:** RE: Tumour-site Concordance and Mechanisms of Carcinogenesis

Thanks for your positive comments, Ivan, and for your specific comments on the draft consensus statement.

Although Robert will be coordinating the response to all comments by the Workshop Participants, I've offered a few perspectives on some of your comments below (a pleasant way to pass the time sitting in Montreal airport on my way home from Lyon)...

Dan K.

From: Rusyn, Ivan [mailto:IRusyn@cvm.tamu.edu]

Sent: July-16-16 12:19 PM

To: Robert Baan BaanR@visitors.iarc.fr; Cogliano.Vincent@epamail.epa.gov; kavlock.robert@epa.gov; Daniel Krewski <a href="mailto:kavlo

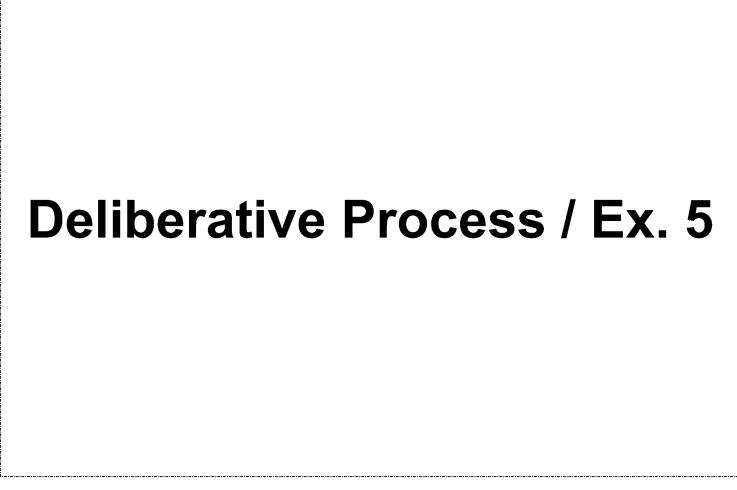
Cc: straif@iarc.fr; Personal Email / Ex. 6

Subject: RE: Tumour-site Concordance and Mechanisms of Carcinogenesis

Dear Robert,

Great job. Congratulations!

Deliberative Process / Ex. 5



Thank you! Ivan

From: Robert Baan [mailto:BaanR@visitors.iarc.fr]

Sent: Friday, July 15, 2016 3:52 PM

To: banks@icgeb.org; frederick.beland@fda.hhs.gov; Personal Email / Ex. 6 | boslandm@uic.edu; bucher@niehs.nih.gov; caldwell.jane@epa.gov; Cogliano.Vincent@epamail.epa.gov; demarini.david@epa.gov; bice.fubini@unito.it; bdgold@pitt.edu; hecht002@umn.edu; k.hemminki@dkfz.de; mark.hill@rob.ox.ac.uk; Personal Email / Ex. 6 ; Agnes Kane@Brown.edu; kavlock.robert@epa.gov; dkrewski@uottawa.ca; lambert@oncology.wisc.edu; ron.melnick@gmail.com; Personal Email / Ex. 6 r332@georgetown.edu; martynts@uclink4.berkeley.edu; lstayner@uic.edu; ullrich@rerf.or.jp; p.vineis@imperial.ac.uk; waalkes@niehs.nih.gov; lzeise@oehha.ca.gov; Bernard.Stewart@sesiahs.health.nsw.gov.au; Personal Email / Ex. 6 pascale.h.lajoie@gmail.com; zoughoolm@ksauhs.edu.sa; Personal Email / Ex. 6 jllittle@uottawa.ca; bmilton@risksciences.com; malzough@uottawa.ca; Nicholas.Birkett@uottawa.ca; Harri.Vainio@hsc.edu.kw; Rusyn, Ivan < IRusyn@cvm.tamu.edu >; Personal Email / Ex. 6 workshops100+@iarc.fr; Personal Email / Ex. 6 cphra@uottawa.ca; bullrich@utmb.edu; Personal Email / Ex. 6 workshops100+@iarc.fr

Subject: Tumour-site Concordance and Mechanisms of Carcinogenesis

Dear colleagues,

It has been a long time since we had contact; I hope you are doing fine.

PBI / Ex. 4

We hope you can endorse the Consensus Statement and the final results presented in the attached documents.

With your support, we will bring this project to a close.

I hope to hear from you, wishing you pleasant holidays.

With my best regards,

Robert

Message

From: Cogliano, Vincent [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=51F2736376AC4D32BAD2FE7CFEF2886B-COGLIANO, VINCENT]

Sent: 1/14/2016 8:55:28 PM

To: Wolfe, Mary (NIH/NIEHS) [E] [wolfe@niehs.nih.gov]

Subject: RE: draft EC minutes

Attachments: NTP-EC-Minutes_10Dec2015_Draft3-revVJC.docx

Hello Mary—Attached is a markup of the EPA section. Thanks!—Vince

From: Wolfe, Mary (NIH/NIEHS) [E] [mailto:wolfe@niehs.nih.gov]

Sent: Monday, January 11, 2016 2:06 PM

To: Cogliano, Vincent < cogliano.vincent@epa.gov>

Subject: draft EC minutes

Vince,

Hope 2016 is starting off well. Please review the section of the NTP Executive Committee minutes for 12/11/15, pages 3-4, 3. **Deliberative Process / Ex. 5** and provide any needed revisions (total content $\sim 1/2$ page). If possible, we'd like your comments by this Thurs, 1/14/16.

Thanks, Mary From: Flowers, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1A4411C874D041B9A8BADFC32B91BD70-FLOWERS, LYNN]

Sent: 5/17/2017 8:02:19 PM

To: Crofton, Kevin [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a23824ad1d466c92e9a86b0485a93e-Crofton, Kevin]; Egeghy, Peter

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=49d8224195e64a72882077b1c07940be-Egeghy, Peter]

CC: Cogliano, Vincent [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=51f2736376ac4d32bad2fe7cfef2886b-Cogliano, Vincent]; McQueen,

Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a023f4d48ee4e1f8b758fa87310f703-McQueen, Jackie]; Lobdell, Danelle

[/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=091b44f2b8294a5ab4d782023a4fb852-Lobdell, Danelle]

Subject: FW: ORD FOIA documents for possible discretionary release

Attachments: image2017-05-16-143022.pdf

Importance: High

Hi Kevin and Peter: Norman indicated in his email below that he contacted you separately. Let's all take a minute to digest this request – and inform management. Then make a decision about how to respond.

I replied to Norman that we would get back with him soon. Call me if you have other ideas.

Lynn

Lynn Flowers, PhD, DABT Associate Director for Science Office of Science Policy US EPA Washington, DC 202-564-6293

From: Adkins, Norman

Sent: Wednesday, May 17, 2017 12:47 PM

To: Flowers, Lynn <Flowers.Lynn@epa.gov>; Cogliano, Vincent <cogliano.vincent@epa.gov>; McQueen, Jacqueline

<McQueen.Jacqueline@epa.gov>; Lobdell, Danelle <Lobdell.Danelle@epa.gov>

Cc: Evanko, Peter < Evanko. Peter@epa.gov>

Subject: FW: ORD FOIA documents for possible discretionary release

Importance: High

Lynn, Vince, Jackie, and Danelle,

My name is Norman Adkins and Peter Evanko and I are supporting the overall FOIA program with ORD. I received a message from EPA's Office of General Counsel (OGC). They reached out concerning a FOIA

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

I have already sent this message to Peter Egeghy and Kevin Crofton.

Deliberative Process / Ex. 5

Deliberative Process / Ex. 5

Exemption 1: Information that is classified to protect national security.

Exemption 2: Information related solely to the internal personnel rules and practices of an agency.

Exemption 3: Information that is prohibited from disclosure by another federal law.

Exemption 4: Trade secrets or commercial or financial information that is confidential or privileged.

Exemption 5: Privileged communications within or between agencies, including those protected by the:

- 1. Deliberative Process Privilege (provided the records were created less than 25 years before the date on which they were requested)
- 2. Attorney-Work Product Privilege
- 3. Attorney-Client Privilege

Exemption 6: Information that, if disclosed, would invade another individual's personal privacy.

Exemption 7: Information compiled for law enforcement purposes that:

- 7(A). Could reasonably be expected to interfere with enforcement proceedings
- 7(B). Would deprive a person of a right to a fair trial or an impartial adjudication
- 7(C). Could reasonably be expected to constitute an unwarranted invasion of personal privacy
- 7(D). Could reasonably be expected to disclose the identity of a confidential source
- 7(E). Would disclose techniques and procedures for law enforcement investigations or prosecutions
- 7(F). Could reasonably be expected to endanger the life or physical safety of any individual

Exemption 8: Information that concerns the supervision of financial institutions.

Exemption 9: Geological information on wells.

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What are exclusions?

Congress has provided special protection in the FOIA for three narrow categories of law enforcement and national security records. The provisions protecting those records are known as "exclusions." The first exclusion protects the existence of an ongoing criminal law enforcement investigation when the subject of the investigation is unaware that it is pending and disclosure could reasonably be expected to interfere with enforcement proceedings. The second exclusion is limited to criminal law enforcement agencies and protects the existence of informant records when the informant's status has not been officially confirmed. The third exclusion is limited to the Federal Bureau of Investigation and protects the existence of foreign intelligence or counterintelligence, or international terrorism records when the existence of such records is classified. Records falling within an exclusion are not subject to the requirements of the FOIA. So, when an office or agency responds to your request, its response will encompass those records that are subject to the FOIA.

Thanks again!

Norman Adkins, CCEP, CGFM, PMP U.S. Environmental Protection Agency Office of Research and Development

Office: (919) 541-0479

Mobile: Personal Phone / Ex. 6

Fax: (919) 541-4002

From: Margolis, Alan

Sent: Tuesday, May 16, 2017 2:51 PM

To: Adkins, Norman <adkins.norman@epa.gov>

Cc: Margolies, Jennifer <Margolies.Jennifer@epa.gov>; Miller, Kevin <Miller.Kevin@epa.gov>

Subject: ORD FOIA documents for possible discretionary release

Norman.,

Thanks for your help. As we discussed, please circulate to Matt Martin, Kevin Crofton and Peter Egeghy.

Attorney Work Product / Ex. 5

I am happy to discuss the case and can be reached (202) 431-9304. Please cc: any written response to Kevin Miller. Thanks for your assistance in this matter.

Margolis, Alan

From:

Kolsky, Joshua (USADC) < Joshua.Kolsky@usdoj.gov>

Sent:

Monday, May 08, 2017 2:29 PM

To:

Margolis, Alan

Subject:

FW: EELI v. EPA, No. 16-2621

Alan,

Deliberative Process / Ex. 5

7037

From: Chaim Mandelbaum [mailto: Personal Email / Ex. 6)]

Sent: Monday, May 8, 2017 2:25 PM

To: Kolsky, Joshua (USADC) < JKOLSKY@usa.doj.gov>

Subject: Re: EELI v. EPA, No. 16-2621

Deliberative Process / Ex. 5

Thank you, Chaim

Chaim Mandelbaum

Attorney-at-Law

726 N Nelson St, Suite 9 Arlington, VA 22203 Telephone: 703-577-9973 Entail: <u>Chaim12@gmail.com</u>

On Fri, May 5, 2017 at 4:29 PM, Kolsky, Joshua (USADC) < Joshua. Kolsky@usdoj.gov> wrote:

Attorney Work Product / Ex. 5

Attorney Work Product / Ex. 5

Regards,

Josh

Joshua Kolsky

Assistant United States Attorney

District of Columbia

555 Fourth St., N.W.

Washington, D.C. 20530

Phone: (202) 252-2541

Fax: (202) 252-2599

Email: joshua.kolsky@usdoj.gov

